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PATENT APPLICATION
ATTORNEY DOCKET NO.: 28384/36668

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

Eva-Maria Mandelkow et al.

Serial No: 09/640,737

Filed: August 17, 2000

For: Novel Tools for the Diagnosis and Treatment of Alzheimer's Disease

Art Unit: 1646

Examiner: O. N. Chernyshev

CERTIFICATE OF MAILING
(37 C.F.R. § 1.8)

I hereby certify that this paper is being deposited as First Class Mail on October 15, 2002 in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231.

Thomas J. Wrona, Ph.D.

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This paper is submitted in response to an Office Action setting forth a restriction requirement restricting the claims of the application. The Office Action was dated August 6, 2002, and set a shortened statutory period of one month for the response. The response was due September 6, 2002. A petition for a two month extension of time is submitted herewith extending the due date for response to November 6, 2002. Therefore, this response is timely filed.

I. Response to Restriction Requirement.

The Office Action set forth a 25-way restriction requirement. The restriction is premised on the assertion that claims 37, 38, 44, and 45 are each improper Markush claims. The Office Action asserts the plurality of amino acid sequences recited in these claims lack a common utility which is based upon a shared structural feature lacking from the prior art. Based on this assertion, the claims are restricted to one member of the Markush group. Each member of the Markush group allegedly is a distinct invention because they are unrelated. Applicant is asked to elect one member of the group for examination.

In response to the restriction requirement, Applicants provisionally elect examination of Group XXII (residues 259-267 in SEQ ID NO:1). This election is made ***with traverse***.

II. Traversal of Restriction Requirement.

Applicant requests that the restriction requirement be reconsidered because (1) the twenty five different peptides share a common utility based upon a shared structural feature lacking from the prior art and (2) even if the twenty five different peptides are distinct or independent invention, the examiner has not shown that a serious burden would be required to examine all of the members of the Markush group.

The peptides of the Markush group share a common utility. Each peptide is useful in producing antibodies specific to the tau protein. Moreover, the inventor's discovery that certain serine and threonine residues are phosphorylated in Alzheimer tau protein renders certain peptides containing such residues particularly useful as epitopes for producing antibodies that are useful in distinguishing between normal tau protein and Alzheimer tau protein. The peptides of the Markush group all contain such serine or threonine residues. Thus, they are share the common utility of being useful in producing antibodies to regions of the tau protein shown to be useful in distinguishing between normal tau protein and Alzheimer tau protein.

Furthermore, the common utility is based upon a shared structural feature lacking from the prior art. Each peptide of the Markush group is derived from the same protein (tau) having the sequence of SEQ ID NO:1. Furthermore, although the sequence of each peptide is different, they all share a common structural feature (serine-proline or threonine-proline). As discussed above, this common feature provides a common utility for the peptides. Moreover,

this shared common structural feature was not known in the art to be important in the formation of Alzheimer tau protein or for production of antibodies that would be able to distinguish normal tau protein from Alzheimer tau protein. Thus, the peptides of the Markush group have a common utility based upon a shared structural feature lacking from the prior art.

Even if the peptides were distinct or independent inventions, the Examiner has not shown that a serious burden would be required to search and examine all of the peptides of the Markush group. M.P.E.P. § 803 provides:

> If the search and examination of an application can be made without serious burden, the Examiner **must** examine it on the merits, even though it includes claims to distinct or independent inventions. *(Emphasis added.)*

The Applicant submits that a generic search for tau protein as it relates to Alzheimer's disease would identify all art relating to various phosphorylated epitopes of tau associated with this pathology.

Applicant respectfully submits that the Examiner has not shown that the criteria for a proper restriction requirement have been satisfied. Initially, the Examiner has not shown that it would be a serious burden to search and examine the Markush group. Paragraph 4 of the Office Action states that the individual peptides of the Markush group "have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and non-coextensive literature searches." However, other than this blanket statement, the Office Action fails to provide any showing that it would be a serious burden on the Examiner to search and examine each member of the Markush group. The Office Action fails to show that the peptides of the Markush group are recognized as divergent subject matter or that non-coextensive literature searches are required. Indeed, all of the peptides are fragments of the same protein, tau, which is provided in SEQ ID NO:1.

Furthermore, the statement in Paragraph 4 is contradictory with other statements in the Office Action itself. Paragraph 2 states that the individual peptides all **belong to the same class and subclass** (class 530, subclass 30), which is inconsistent with the statement that the individual peptides of the Markush group "have acquired a separate status in the art as shown by their **different classification**." Thus, given the lack of any showing of an undue burden on the Examiner along with the indication that all of the peptides are from the same

class and subclass, the restriction between each individual tau peptide is improper.

Therefore, because (1) the individual peptides of the Markush group share a common utility based upon a shared structural feature lacking from the prior art and (2) even if the twenty five different peptides are distinct or independent invention, the examiner has not shown that a serious burden would be required to examiner all of the members of the Markush group, Applicant respectfully requests that the Examiner reconsiders the restriction requirement.

Respectfully submitted,

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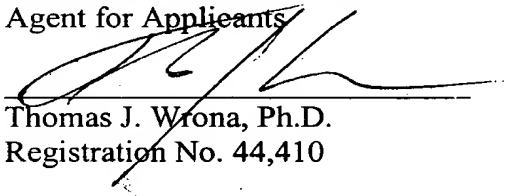

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